

## REMARKS

Reconsideration of the application as amended is requested. An objection was raised with respect to the Abstract. Applicants have presented amendments to the Abstract that are believed to address all of the objections.

An objection was raised with respect to a typographical error in claim 6. This claim has been amended to identify "the tubing", as suggested in the Office Action.

### Rejections of the claims under 35 U.S.C. §112

Claim 13 was rejected under 35 U.S.C. §112 as not being enabled by the written description, particularly the language "that the tubing bed body member (25) coaxially enlases the rotor (3) by an amount of  $360^0$  divided by the number of conveyor rollers." It was pointed out that the body member 25 shown in FIG. 2 enlases the rotor 3 by more than  $180^\circ$ , which is greater than 360 degrees divided by the number of rollers (3), or greater than  $120^\circ$ . It can first be pointed out that if the body member enlases the rotor by more than  $180^\circ$ , it necessarily also enlases the rotor by  $120^\circ$ . As explained at Para. 0025 of the specification, the tubing bed body member must enlase the rotor sufficiently so that at least one conveyor roller is actively squeezing a section of tubing. If the body member enlases the rotor by the  $240^\circ$  degrees depicted in Fig. 2, then at least one, and actually all, of the rollers is active. Likewise, if the body only extended through  $120^\circ$  one of the rollers will always be aligned with or enlaced by the body member – i.e., as each roller 33a-33c is successively rotated into alignment with the  $120^\circ$  segment of tubing bed body member.

With this understanding, it is clear that the language of claim 13 is in fact enabled by the specification and drawings. It should be further clear that the proposed amendment requiring that the body member interlace by an amount greater than 180 degrees is not what is called for in claim 13 or reflected in the specification. However, in order to eliminate any misunderstanding with respect to the scope of claim 13, this claim has been amended to indicate that the tubing bed body member enlaces the rotor by an angle that is at least an amount of  $360^0$  divided by the number of conveyor rollers. Thus, in the illustrated embodiment, the apportioned amount would be  $120^0$  and the body member encircles or enlaces by about  $240^0$ , which is "at least" the apportioned amount. Claim 13 is fully supported and enabled by the present disclosure.

Claims 8, 12 and 14 were rejected under Section 112 as being indefinite. With respect to claim 8, exception was taken to the repeated reference to the "squeezed tubing section." Applicants have amended this claim to indicate that the "mutual force action" is achieved by the rollers and the squeezed tubing section. As explained at Para. 0023 of the specification, it is the radially outward force produced by the rollers pressing against the tubing sections that help hold the tubing bed body member 25 fixed to the frame 1. Thus, it is the mutual force action of the rollers and squeezed tubing section that provides the necessary radial force.

Claim 12 was rejected for its reference to "the particular tubing section." This claim has been amended to recite the "at least one flexible tubing section" originally set forth in independent claim 1.

Claim 14 was rejected as indefinite due to the claim's reference to a range of angles and a particular preferred angle within that range. The particular angle has been removed from this claim, leaving the range of angles from 210-270 degrees.

With the above noted amendments to claims 8, 12 and 14 it is believed that all of the rejections under Section 112 have been addressed and that these claims are definite and unambiguous.

#### The Rejections under 35 U.S.C. §102

Claims 1, 2, 4-6 and 12-14 were rejected as anticipated by U.S. Patent No. 5,846,061 (the '061 Patent). Applicants have amended claim 1 to substantially incorporate the limitations of claim 14. Claim 14 has thus been cancelled without prejudice to treatment in a further application. Applicants have further amended claims 5-10, 12 and 13 to depend from claim 1. Applicants have also amended claim 11 to depend from claim 10 to provide antecedent basis for the "groove-like recesses" term.

Claim 14 has been rejected as anticipated by the '061 Patent, with reference to an enlarged excerpt of FIG. 3 of that reference. In this enlarged figure, the angular arrangement of the rollers 26 was erroneously equated with the claimed inlet region and outlet region. It is apparent from FIG. 3 that the rollers do not squeeze the tubing in their illustrated positions. It is after the left side roller 26 has been rotated (clockwise) that it begins to compress the tubing. Similarly, it is only after a counterclockwise rotation that the right side roller begins to compress the tubing. In fact, the drawing of FIG. 3 does not depict any deflection of the tubing at the point of contact with the lower two rollers (in contrast to the deflection shown at the upper

roller). Thus, it is clear that the rollers 26 themselves are not oriented at the inlet and outlet regions, but are instead offset outside those regions.

Contrast the appearance of the rollers 26 and tubing 62 in FIG. 3 of the '061 Patent to the appearance of the rollers 33c, 33a and tubing 43 in FIG. 2 of the present application. Although the rollers 33a-33c of the present application are depicted in the same angular orientation as the rollers 26 of the '061 Patent, the impact on the respective tubing is quite noticeably different. With the present invention, the tubing 43 is compressed or squeezed at both the inlet and the outlet. In the device of the '061 Patent, the tubing can only be squeezed at either the inlet or the outlet, but not at both locations simultaneously. The reason for this limitation in the '061 Patent is that the inlet region and the outlet region are not "offset around the axis of rotation of the rotor ... by 210° to 270°." Instead, it appears that the actual inlet and outlet regions – i.e., the locations at which the tubing is actually squeezed by the rollers – are offset by about 200° or less.

In fact, due to the construction of the device in the '061 Patent, it appears that the occlusion member or stator 28 cannot be configured as defined in Applicants' claim 1 because such a configuration would prevent assembly of the stator on the housing 14. As explained at col. 4, lines 29-56 the stator 28 is mounted on occlusion rings 32a, 32b that are attached to a respective side wall 16a, 16b of the housing 14. The occlusion rings 32 are "made from high strength 6061 aluminum plate", while the stator 28 is "made from extruded 6061 aluminum". Col. 6, lines 36-39. Thus, the '061 Patent does not contemplate that the stator 28 can somehow deform to engage the rings 32. Instead, the stator has the configuration shown in FIG. 3 of the patent so that it can be pivoted (about pin 34) and pressed by clamps 38 into contact with the

rings. (See, col. 4, lines 47-51). If the stator 28 of the '061 Patent had the configuration of the tubing bed body member of Applicants' claim 1 the device could not be assembled.

Thus, the stator 28 in the '061 Patent does not and cannot meet the limitation of amended claim 1 that the inlet and outlet regions are offset by between  $210^{\circ}$  and  $270^{\circ}$ . Furthermore, as explained modifying the stator 28 to meet this limitation would destroy the functionality of the device disclosed in that patent. As discussed in the present application, the structure of the tubing bed body member reduces the effects of torque variations by the drive motor, while providing a gentle and high efficiency pumping action that is especially suited for conveying delicate cell suspensions. See, e.g., Paras. [0005], [0020].

Since the stator 28 in the '061 Patent cannot meet the structural limitations set forth in claim 1, this reference cannot anticipate this claim or any of its dependent claims. Moreover, as explained the structure of the device in the '061 Patent cannot be modified to meet Applicants' claimed invention so there can be no prima facie case for obviousness based on this reference.<sup>1</sup> It is therefore believed that claim 1 and all of its dependent claims 2-13 and 15 are allowable.

While the patentability of amended claim 1 inures to the benefit of its dependent claim, certain of these claims are patentable on their own merits. For instance, claims 3 and 15 each recite that the tubing bed body member passes at the

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<sup>1</sup> It can be noted that the other reference relied upon in the obviousness rejections (Davis et al., No. 7,118,203) shows an occlusion 62 that is even more open than the stator in the '061 Patent. Judging from FIG. 7 of the '203 Patent, it appears that the occlusion inlet and outlet are spaced less than  $180^{\circ}$  apart. Thus, this reference adds nothing to any attempted obviousness argument against Applicants' claim 1

outlet region from a concave to a convex shape in a smooth transition. These claims were said to be obvious in view of the '061 Patent.

The outlet in the device of the '061 Patent (the region adjacent the right roller 26) is entirely concave. Although the outlet region of the stator 28 expands, it is still a concave shape, as evidenced by the smooth un-squeezed interface between the tube 62 and that region of the stator. Thus, since the '061 Patent does not disclose an outlet region that transitions from a concave to a convex shape it cannot anticipate claims 3 or 15.

Moreover, there is no suggestion to modify that outlet region of the stator 28 to a convex shape. The outlet region of the stator is made concave to conform to the curvature of the tube 62 as it bends from the outlet fitting 66 to the stator 26, presumably to prevent kinking of the tube. Removing that concave shape would eliminate the critical support for the tube at this region. (It can be appreciated that the same issue is not present at the inlet region of the stator 28 because the tube 62 rises unbent from the inlet fitting 60, as seen in FIG. 3). In support of the obviousness allegation it was suggested that providing a concave-convex transition would have been an obvious modification to "avoid sharp turns/edges and thus tearing of the tubing." However, it should be apparent from FIG. 3 of the '061 Patent that the addition of the larger concave portion achieves that function. The large radius concave portion allows the bent tubing to avoid sharp turns as well as any risk of tearing. There would certainly be no reason to eliminate that double concave structure of the stator 28 simply to add a convex portion that would be incapable of supporting the curved section of tubing exiting the stator 28. Thus, claims 3 and 15 cannot be rendered obvious in view of the '061 Patent.

Claim 4 was also said to be anticipated, but this conclusion was based on an erroneous construction of the inlet and outlet regions in the device of the '061 Patent. As indicated above, the rollers 26 themselves were regarded as the inlet and outlet of the device. However, Applicants' claims refer to the inlet and outlet regions of the tubing bed body member. Thus, as explained above, these regions are actually offset from the two lower rollers 26. Moreover, as further explained only one of the lower rollers can squeeze a section of tubing, either at the inlet or at the outlet. The device in the '061 Patent is not capable of squeezing the tube at both the inlet and the outlet simultaneously. Consequently, the '061 Patent does not disclose structure in which a roller is disposed simultaneously in both the inlet region and the outlet region of the tubing bed body member. The '061 Patent cannot anticipate claim 4.

Claim 5 recites that the body member is in the shape of an omega ( $\Omega$ ), which is best seen in FIG. 3 of the present application. Although this claim was rejected as anticipated by the '061 Patent, it is clear that the stator 28 is not in the shape of an omega, but more in the nature of an open U-shape. In order to achieve an omega shape, the stator 28 of the '061 Patent would need to curve further inward beyond the positions shown in FIG. 3 of that reference. The inlet side of the tube extends vertically upward to the open mouth of the stator 28, while the outlet side of the tube actually flares outward from the mouth of the stator, as FIG. 3 reveals. This is not an omega shape, so the '061 Patent cannot anticipate claim 5.

#### The Rejections under 35 U.S.C. §103

Claims 7-11 were rejected as obvious in view of the combination of the '061 patent with the U.S. Patent No. 7,118,203 (the '203 Patent). As explained above, the

primary reference of the '061 patent fails to disclose every element of claim 1, most particularly the offset of the inlet and outlet regions of the tubing bed body member. As indicated in the footnote above, the occlusion 62 of the '203 Patent is even more wide open than the stator of the '061 Patent, so the '203 Patent also fails to disclose every limitation of claim 1. Since claim 1 is both novel and non-obvious in view of the '061 and the '203 Patents, whether taken alone or in combination, then the patentability of claim 1 inures to the benefit of dependent claims 7-11.

Furthermore, the dependent claims define features that are not found in the cited combination of references. For instance, claim 7 was said to be obvious in view of the alleged disclosure in the '203 Patent of two legs (140, 142) that are resiliently elastic in the radial direction and that are provided with notch elements (said to be "clearly seen in figure 7"), by means of which the occlusion 62 can be snapped into un-identified cut-outs in the frame 64 (referring to figures 6 and 7).

The inability to identify any structure that corresponds to the "cut-outs" recited in claim 7 is revealing. There are no such cut-outs in the member 64, or more pertinently in the frame or holder 56 that is disclosed as supporting the occlusion 62. (See, col. 7, lines 62-64). In the office action, the element 64 is identified as the support frame. The element 64 is a support spring system that is separately mounted to the holder 56. The spring system also engages a leg of the occlusion 62, as shown in FIG. 6, to elastically support one end of the occlusion. See, col. 9, lines 20-36. The other end of the occlusion includes openings 106 that engage teeth 105 in the holder 56. See, col. 5, lines 54-58. There is no snap-fit connection, no cut-outs in the frame 56 and no notch elements in the occlusion 62 at this leg.



It was further suggested that the assigned legs 140, 142 of the occlusion 62 are resiliently elastic in the radial direction, with reference to col. 8, lines 49-60 of the '203 Patent. However, this excerpt refers to the interface between the fingers 142 and the base portion 140. It is the base portion that is engaged to the holder 56, as explained at col. 8, lines 3-6. "Occlusion fingers 142 extend from base portion 140," (col. 8, lines 7-8) and it is the fingers that are permitted to flex (col. 8, lines 51-55). Thus, the excerpt from the '203 Patent cited to support the obviousness rejection of claim 7 does not refer to the connection between the occlusion 62 and the holder 56 or even the spring system 64. Moreover, given the manner in which the occlusion is mounted to the holder 56 there is no need for the ends of the occlusion to be "resiliently elastic in radial direction". The spring system 64 provides all the flexibility needed to hold the occlusion 62 in place and to ensure that the occlusion 62 holds its proper position relative to the tubing being occluded. Moreover, since there is no "snap-on connection" disclosed in the '203 Patent there is no need for the ends of the occlusions to be "resiliently elastic in radial direction" as defined in claim 7. It is believed that the combination of the '061 and '203 Patents fails to provide a prima facie case for obviousness of claim 7 and that this claim is therefore patentable over the art of record.

### Conclusion

The primary reference, the '061 Patent, fails to disclose all of the structural limitations recited in claim 1 as amended. The '203 Patent also fails to provide the missing structure, so both cited references fail to anticipate or render obvious claim 1. Moreover, as explained above, certain details in the dependent claims are not found in

the applied references, whether taken alone or in combination. It is therefore believed that all of the pending claims 1-13 and 15 are patentable, and that action toward a Notice of Allowance is appropriate.

Respectfully submitted,

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